

Comparison of Peri-tonsillar Injection of Tramadol with Adrenaline Vs Injection of Normal Saline (Placebo) Before Tonsillectomy in Reducing Per-operative Haemorrhage and Post-operative Pain

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¹ Analysis/Interpretation/Discussion

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Abstract

Objective: This study aimed to find out the efficacy of adrenaline and tramadol in controlling perioperative hemorrhage and postoperative pain respectively.

Materials and Methods: A randomized controlled trial was conducted in the ENT department of Benazir Bhutto Hospital Rawalpindi for 6 months (21-11-2016 to 21-5-2017). The data was collected by operating surgeons. A total of 60 patients were included in the study with 1:1 randomization. Simple random sampling was used for the Selection of patients. Patients were divided into two groups. Group A was provided with the peri-tonsillar injection of tramadol with adrenaline while Group B was provided with normal saline injection (Placebo). Both groups were followed for 6 hours to measure mean pain scores and mean hemostasis time. After approval from the ethical review board, consent forms were distributed to patients. An Independent t-test was applied for the comparison of different variables.

Results: Among all patients 60(100%), 25 (41%) males, and 35(59%) females. The mean age of patients was 12.2 years \pm 4.49 SD. The mean time required for hemostasis was 4.9 minutes \pm 1.92 SD. The mean pain scores were 1.3 (mild pain) \pm 1.12 SD. A statistically significant difference was found with time ($p=0.01$), mean pain ($p=0.00$), weight ($p=0.00$) and age ($p=0.00$) while insignificant with gender ($p=0.06$).

Conclusion: Peri-tonsillar injection of tramadol with adrenaline during tonsillectomy leads to a significant reduction in per-operative hemorrhage and post-operative pain as compared to injection of normal saline.

Keywords: Tonsillectomy, Tonsillitis, Saline, Peri-tonsillar, Adrenaline.

Introduction

Tonsillectomy is one of the most frequent surgical procedures performed in the otorhinolaryngology department. It involves the surgical removal of palatine tonsils which can be done by various techniques like dissection and snare method, electrocautery, radio frequency ablation, harmonic scalpel, carbon-dioxide laser, and microdebrider.

Postoperative pain and preoperative hemorrhage are the most frequent complications of tonsillectomy. In the early postoperative period, pain is considered to be the major cause of morbidity. Patients experience odynophagia for at least seven to ten days after tonsillectomy resulting in decreased oral intake, dehydration as well as extended hospitalization. Different methods of minimizing postoperative pain have been proposed including the use of oral analgesics¹, infiltration of local anesthetics, and analgesics such as levobupivacaine², ketamine³, and tramadol.^{4,5,6} Recent studies have shown that natural ingredient such as honey^{7,8,9} is found to be effective in reducing postoperative pain and analgesic requirements in patients after tonsillectomy. The most dreadful and frequent complication of tonsillectomy is hemorrhage which can be divided into primary, reactionary, and secondary types. Primary hemorrhage is at the time of operation, reactionary hemorrhage is within 24 hours after tonsillectomy, and secondary hemorrhage is after 24 hours up to the tenth postoperative day. To minimize these complications, preoperative preparation of the patient is mandatory. To secure hemostasis during a tonsillectomy, several techniques including ligation, diathermy, and cauterization are used. In addition, hemostatic agents such as bismuth subgallate and adrenaline are helpful to control bleeding and minimize perioperative hemorrhage risk. Adrenaline¹⁰ is a potent vasoconstrictor that retracts blood vessels in the tonsillar bed and decreases blood flow. It also stimulates platelet aggregation in blood clot formation and thus helps in hemostasis.

A study has been conducted in Iran to find out the efficacy of adrenaline¹¹ and tramadol¹¹ in controlling perioperative hemorrhage and postoperative pain respectively. Meantime required to achieve hemostasis by using adrenaline in minutes was observed to be 8 ± 2 and with normal saline was 15 ± 3 with a difference of 7 min. Whereas mean value for VAS pain score at 6 hours using tramadol was 45 ± 10 and with normal saline was 55 ± 10 with a difference of 10.

No documented study was found on this topic in Pakistan. This study has been conducted in Iran only, so this study will be the first of its kind in our population. A tonsillectomy is one of the commonest procedures performed in the ENT department and postoperative pain and perioperative hemorrhage are some of its main complications. This study will emphasize reducing these complications by better treatment options.

Materials and Methods

Approval has been taken from the institutional research forum of Rawalpindi Medical University and informed consent was taken from all patients. A detailed history was taken about recurrent tonsillitis from patients admitted in the ward for tonsillectomy. Patients admitted with a confirmed diagnosis of recurrent tonsillitis with age ranging from 6-20 years and both genders were included in the study whereas those patients who had comorbidities i.e. hypertension, coagulopathies, and hepatic disorders, those taking drugs like heparin and warfarin, and any analgesic drug in last 24 hours prior to the procedure was not included in our study. A total number of 60 patients aged between 6-20 years of ASA (American Society of Anesthesiologists) 1-2 status were randomly divided into two study groups through simple random sampling using a random number list generated through SPSS. All of the patients were operated on under general anesthesia by using the standard anesthetic protocol. After maintaining proper position for tonsillectomy, in group A (n=30), the total solution containing a mixture of 1:200,000 adrenaline in a dose of $2 \mu\text{g}/\text{kg}$ and $2 \text{mg}/\text{kg}$ tramadol was injected before giving incision with a 23 G needle using aspiration injection technique in the peri-capsular plane. In the second group B (n=30), 4ml normal saline was injected in the peri-capsular plane on each side. It was performed in a double-blind way. After giving the peritonsillar injection, we waited for one minute. The operation was started by giving a mucosal incision using a cold knife.

A tonsillar dissector was used to separate the upper pole of the tonsil from peritonsillar tissue. Dissection was continued by holding the tonsil from its upper pole and by pulling the tonsil downward and medially until the lower pole was reached. By using a tonsillar snare, the pedicle was cut and the tonsil removed. After removing the tonsil, gauze was placed in the fossa for a few minutes. The second tonsil was removed by the same procedure. Hemostasis was

achieved by using sutures to tie the bleeding point. At the end of tonsillectomy, two things were noted in both groups i.e. number of ties applied to the bleeding point and time to achieve hemostasis. Patients in both the groups were evaluated for pain levels on a visual analogue pain scale (VAS) postoperatively at 2, 4, and 6 hours respectively in the ward. Patients with a VAS score of 5 or above (moderate to severe pain) were given an injection of diclofenac sodium 1.5mg/kg via the intramuscular route. No other analgesic was given.

Results

The study included a total of 60 patients with 1:1 ratio randomization in each group. Among all the patients 60(100%), there are 25(41%) males and 35(59%) females. The mean age of patients was 12.2 years±4.49 SD. The mean weight of patients was 30.5Kg±8.16 SD. The mean time required for hemostasis was found to be 4.9 minutes±1.92 SD. The mean pain scores were found to be 1.3 (mild pain) ±1.12 SD. (Table 1)

The study found out that among all the patients in group A 30(50%), there were 15 (25%) males and 15 (25%) females. Similarly, in group B 30 (50%), there were 10 (33%) males and 20 (67%) females. (Figure 1)

The study found out that mean postoperative pain in Group A is 0.800±0.7143 while mean postoperative pain in Group B was 1.866±1.224. The difference was statistically significant (p=0.00). (Table 2)

The study found out that the mean time required for hemostasis in Group A was 4.200±1.669 while the mean time for hemostasis was 5.766±1.869 in Group B. The difference was statistically significant (P=0.001). (Table 3)

The study found out an insignificant difference for gender in both groups (P=0.06) with a mean value of

0.4667±0.507 SD in group A and 0.700±0.466 SD in group B (Table 4).

The study found out that the mean age in group A was found to be 14.30±3.49 SD while 10.23±4.508 SD in Group B. The difference was statistically significant (p=0.00). (Table 5)

The study found out that the mean weight in Group A was 33.26±7.32 SD while the mean weight in Group B was 27.73±8.12 SD. The difference was statistically significant (p=0.00). (Table 6)

Table 1: Demographic characteristics

Demographic variables	Mean	Standard deviation
Age	12.26	4.49
Weight (Kg)	30.5	8.16
Mean time for hemostasis (minutes)	4.9	1.92
Mean pain scores	1.3	1.12

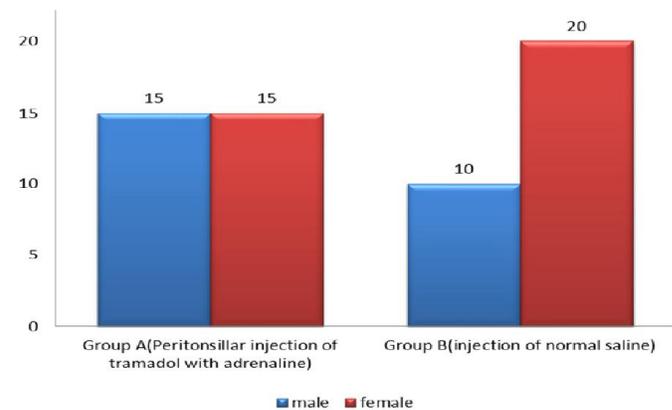


Figure 1: Gender Distribution in both study groups

Table 2: Mean pain scores in both groups

Study groups	N(60)	Mean	Standard deviation	t- value	P-value
Group A (interventional group)	30	0.800	0.7143	-4.122	0.00
Group B (Placebo group)	30	1.8667	1.2242		

Table 3: Mean time of hemostasis in both groups

Study groups	N(60)	Mean	Standard deviation	t- value	P-value
Group A (interventional group)	30	4.200	1.6691	-3.424	0.001
Group B (Placebo group)	30	5.766	1.8696		

Table 4: Gender stratification

Study groups		N(60)	Mean	Standard deviation	t- value	P-value
Gender	Group A (interventional group)	30	0.4667	0.5074	-1.855	0.06
	Group B (Placebo group)	30	0.700	0.4660		

Table 5: Age distribution in both groups

Study groups		N(60)	Mean	Standard deviation	t- value	P-value
Age	Group A (interventional group)	30	14.300	3.495	-3.905	0.00
	Group B (Placebo group)	30	10.233	4.508		

Table 6: weight distribution in both groups

Study groups		N(60)	Mean	Standard deviation	t- value	P-value
Weight	Group A (interventional group)	30	33.266	7.329	-2.770	0.00
	Group B (Placebo group)	30	27.733	8.123		

Discussion

Post-operative pain and pre-operative hemorrhage are the most frequent complications of tonsillectomy. In the early postoperative period, pain is considered to be the major cause of morbidity. Patients experience odynophagia for at least seven to ten days after tonsillectomy resulting in decreased oral intake, dehydration as well as extended hospitalization. Different methods of minimizing postoperative pain have been proposed including the use of oral analgesics¹, infiltration of local anesthetics, and analgesics such as levobupivacaine², ketamine³, and tramadol.^{4,5} Another dreadful and frequent complication of tonsillectomy is hemorrhage which can be divided into primary, reactionary, and secondary types. Primary hemorrhage is at the time of operation, reactionary hemorrhage is within 24 hours after tonsillectomy, and secondary hemorrhage is after 24 hours up to the tenth postoperative day. To minimize these complications, preoperative preparation of the patient is mandatory. To secure hemostasis during a tonsillectomy, several techniques including ligation, diathermy, and cauterization are used. In addition, hemostatic agents such as bismuth subgallate and adrenaline are helpful to control bleeding and minimize perioperative hemorrhage risk.⁶ Beigh Z et al in the year 2013 did research in which he studied the effects of peritonsillar injection of tramadol and adrenaline before Tonsillectomy in controlling perioperative hemorrhage and postoperative pain respectively. Mean time required to achieve hemostasis by using adrenaline in minutes was observed to be 8±2 and with normal saline was 15±3 with a difference of 7 min. Whereas mean value for VAS pain score at 6

hours using tramadol was 45±10 and with normal saline was 55±10 with a difference of 10. He, therefore, concluded that Peritonsillar injection of tramadol and adrenaline before tonsillectomy was quite effective in reducing perioperative hemorrhage and postoperative pain. Tramadol is a centrally acting drug that has a systemic and local effect. It is effective in the treatment of moderate to severe pain and its effect on peripheral nerves is reported in both clinical and laboratory studies. Tramadol was believed to produce its antinociceptive and analgesic effects via central actions through spinal and supraspinal sites rather than its local anesthetic effect. With the decrease in extracellular sodium concentration, the nerve fiber sensitivity to local anesthetics increases.¹² Jou et al, suggested that tramadol affects both sensory and motor nerve conduction by the same mechanism as that of lidocaine, both acting on the voltage-dependent sodium channels leading to axonal blockage.¹³ However, Mert et al, suggested that tramadol might have a mechanism slightly different from that of lidocaine for producing conduction blocks; the presence of a large concentration of Ca²⁺ in the external medium increases tramadol's activity whereas decreasing lidocaine's activity¹⁴. The local anesthetic effect of topical 5% tramadol makes an easy, safe and comfortable approach for pain management.

Hemorrhage is a very common and usually the most dreaded complication of tonsillectomy which has instigated the use of various types of topical hemostatic agents such as bismuth subgallate and adrenaline to achieve hemostasis and decrease the risk of intra and postoperative bleeding.¹⁵

Various conventional procedures of securing hemostasis like ligation or cauterization do control major bleeders, but sometimes diffused bleeding and capillary oozing may make it difficult for the surgeon

to locate the bleeder and can lead to inefficient hemostasis. This in turn enhances blood loss and prolongs operative time. Adrenaline is used as a common topical hemostatic agent in our region. It is a powerful vasoconstrictor and acts by producing retraction of blood vessels in the tonsillar bed. It also leads to significant platelet aggregation in the formation of a blood clot and has been demonstrated by Hatton to be inexpensive, posing a little risk, and reducing intraoperative bleeding, and hence can be taken as a reasonable hemostatic agent.

Peritonsillar infiltration before incision of tramadol with adrenaline is significantly effective in reducing per-operative hemorrhage and post-operative pain before tonsillectomy as compared to normal saline injection. Therefore the use of tramadol plus adrenaline injection should be further promoted and implemented for routine use in tonsillectomy surgeries.

Conclusion

Peri-tonsillar injection of tramadol with adrenaline is significantly effective in reducing per-operative hemorrhage and post-operative pain before tonsillectomy as compared to normal saline injection.

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